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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,453	07/18/2006	Matthew David Osborne	"BJS-620-412"	4519
23117	7590	04/02/2009	EXAMINER	
NIXON & VANDERHYE, PC			MARVICH, MARIA	
901 NORTH GLEBE ROAD, 11TH FLOOR			ART UNIT	PAPER NUMBER
ARLINGTON, VA 22203			1633	
MAIL DATE		DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/567,453	<b>Applicant(s)</b> OSBORNE ET AL.
	<b>Examiner</b> MARIA B. MARVICH	<b>Art Unit</b> 1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is FINAL.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-16,33-41 and 43-50 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_ is/are allowed.
- 6) Claim(s) 1-16, 33-41 and 43-50 is/are rejected.
- 7) Claim(s) \_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 07 February 2006 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO/SB/06)  
 Paper No(s)/Mail Date 10/31/07; 2/7/06
- 4) Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_
- 5) Notice of Informal Patent Application
- 6) Other: \_\_\_\_\_

**DETAILED ACTION**

Claims 1-16, 33-41 and 43-50 are pending in this application.

***Information Disclosure Statement***

Information Disclosure Statements filed 10/31/07 and 2/7/06 have been identified and the documents considered. The signed and initialed PTO Form 1449s have been mailed with this action. Documents listed on the IDS as Search reports have been considered but have been crossed out so that they will not appear on the face of an issued patent as Search Reports are not considered to be a document under 37 CFR 1.98.

***Specification***

The drawings are objected to because Figure 4 is described in the Brief Description of Drawings as Figure 4A. However, Figure 4 does not contain an A labeled portion. To avoid confusion it would be remedial to amend the brief description to indicate just Figure 4.

***Claim Objections***

Claims 1 and 10 are objected to because of the following informalities: the preamble to claims 1 and 10 should be amended for clarity to, --A method for the *in vitro* culture of a myeloma cell line wherein the method comprises--. Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-11, 14-16, 33, 34, 37-42, 43 and 46-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Field et al (US 6,593,140; see entire document).

Myeloma cells were cultured *in vitro* in media lacking transferrin and tropolone (lipophilic chelator) but in the presence of 0.2 mg/l of ferric ammonium citrate in suspension culture (see e.g. example 5, line 29-31). As depicted in figure 1, the control cultures do not contain chelators. The disclosure of Fields et al states that the cells do not survive after 48 hours. Nonetheless, the cells are cultured in media meeting the requirements of the instant claims. Furthermore, as the media requirements overlap that of the instant claims, one would expect those of Fields et al to be as successful as that of the instant claims. As evidenced by the instant specification, the concentration of 1.25 mg/L of ferric ammonium citrate is about 0.2 mg/L of iron. Hence, the iron concentration is about 0.03 mg/L. The media was serum-free see example 2.

Claims 1-7, 33-41 and 43-50 are rejected under 35 U.S.C. 102(b) as being anticipated by Gorfien et al (US 20060148074; see entire document).

Myeloma cells were cultured *in vitro* in suspension culture in media lacking transferring, lipophilic chelators and nitrogen containing chelators but in the presence of ferric chloride-sodium citrate (see e.g. ¶ 0094). Iron is in the concentration of 0.28 mg/L to 11 mg/L (see e.g. ¶ 0113). As evidenced by the instant specification, the concentration of 1.25 mg/L of ferric ammonium citrate is about 0.2 mg/L of iron.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-16, 33-41 and 43-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Field et al (US 6,593,140; see entire document) in view of Gorfien et al (US 20060148074; see entire document).

Applicants claim a method of culturing myeloma cells in media lacking transferring, lacking lipophilic chelators and lacking synthetic and/or lipophilic nitrogen containing chelators and in the presence of ferric ammonium citrate.

The teachings of Field and Gorfien et al are described above. Gorfien teaches media for culturing myeloma wherein the iron concentration is between 0.28 and 11 mg/L Hence, the iron concentration would be about 1.75-68.75 mg/L of ferric ammonium citrate.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use ferric ammonium citrate as taught by Field et al in the media taught by Gorfien et al

because Gorfien et al teach that it is within the ordinary skill of the art to use particular levels of iron to culture myeloma cells and because Gorfien et al teach that it is within the ordinary skill of the art to use ferric ammonium citrate as a source of iron. In KSR International Co. v. Teleflex Inc., 82 USPQ2d 1385 (U.S. 2007), the Supreme Court particularly emphasized "the need for caution in granting a patent based on a combination of elements found in the prior art," (Id. At 1395) and discussed circumstances in which a patent might be determined to be obvious. Importantly, the Supreme Court reaffirmed principles based on its precedent that obviousness in part is predicated on use of particular known techniques that are recognized as part of the ordinary capabilities of one skilled in the art. In the instant case, Gorfien and Field et al are both directed at methods of culturing myeloma cells. The combination of the two represents the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." (Id. At 1395.) Based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARIA B. MARVICH whose telephone number is (571)272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1633

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Maria B Marvich, PhD  
Primary Examiner  
Art Unit 1633

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Primary Examiner, Art Unit 1633